

AU InforMed

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Key Inforbits

- New combos and MedWatch
- “Drug Watch” by FDA, coming soon
- New vocabulary words
- Flu vaccine shortage already!?!
- Featured Auburn student
- Graduation salute

NEW DRUGS, and other related stuff ...

New Combo ... Boostrix[®] [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)] by GlaxoSmithKline was approved by the FDA May 3, 2005. It is the first of this type of combination vaccine approved. It is indicated as a single dose to those aged 10 to 18 years old.

www.gsk.com

New Indication ... Ropinirole (Requip[®] by GlaxoSmithKline) has a new indication to treat moderate to severe Restless Legs Syndrome (RLS); it was first approved for Parkinson’s disease in 1997. Restless Legs Syndrome can affect about 10% of the population. It is characterized by an urge to move the legs, usually accompanied by or caused by uncomfortable leg sensations. Symptoms typically begin or worsen during rest or inactivity and are partially/totally relieved by movement. Symptoms often worsen or occur only in the evening or at night, and may disturb sleep. Common side effects include nausea, headache, and vomiting.

<http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01356.html> (FDA Talk Paper)

<http://www.requip.com/> (GlaxoSmithKline web site)

Name change ... just in case you missed it, Ortho-McNeil Neurologics, Inc. is changing the name REMINYL[®] (galantamine HBr) to RAZADYNE[™] (galantamine HBr) for Alzheimer’s disease. The name is being changed to help avoid confusion with the diabetes drug AMARYL[®] (glimepiride). There have been several reports of errors due to the name confusion.

<http://www.razadyne.com/>

MedWatch ... Bedford Laboratories and FDA notified healthcare professionals of the voluntary recall of one lot of **Famotidine Injection**, 20 mg/2 mL (NDC 55390-029-10), Lot# 609336, exp. 04/06, due to a lack of sterility assurance. The product was distributed in August 2004 throughout the U.S. to wholesalers and distributors.

Read the complete MedWatch 2005 Safety summary, including link to the press release, at:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Famotidine>

MedWatch ... The FDA issued a warning about the sale of **counterfeit** versions of Lipitor[®], Viagra[®], and an unapproved product promoted as "generic Evista[®]" to U.S. consumers at pharmacies in Mexican border towns. The three drugs were analyzed and found to contain no

active ingredient. Consumers who have any of these counterfeit products should not use them and should contact their healthcare provider immediately.

Read the complete MedWatch 2005 Safety summary, including a link to the FDA

Talk Paper, at:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#counterfeit>

FROM THE MEDICAL LITERATURE ...

Drug Watch ... At least partly in response to the Vioxx[®] debacle, the FDA will be launching a new web page soon; it will appear on an FDA Web page to be called the “Drug Watch.” The Drug Watch is intended to identify drugs for which the FDA is actively evaluating early safety signals, but it is not intended to be a list of drugs that are particularly risky or dangerous for use. A drug on the Drug Watch should not be construed as a statement by the FDA that the drug is dangerous or that it is inappropriate for use. It is intended only to signify that FDA is attempting to assess the meaning and potential consequences of emerging safety information. A draft proposal is at the following web address...

<http://www.fda.gov/cder/guidance/6657dft.htm>

Reviews of Note ...

- Abramowicz M, ed. Drugs for asthma. *Treat Guidelines Med Lett* 2005 May;3(33):33-8.
- Top 200 OTC / HBC brands in 2004. *Drug Topics* 2005 Apr 18;149(8):41-2.
- Keplar KE, Urbanski CJ, Kania DS. Update on personal digital assistant applications for the healthcare provider. *Ann Pharmacother* 2005 May;39(5):892-907.
- Schön MP, Boehncke W-H. Psoriasis. *N Engl J Med* 2005 May 5;352(18):1899-1912.
- Carragee EJ. Persistent low back pain. *N Engl J Med* 2005 May 5;352(18):1891-8.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... **mesotherapy**, literally meaning “middle therapy” but, signifies yet another new approach in the war against diet and exercise. It calls for injections into small fat deposits below the skin surface to “dissolve” them thus, enhancing appearance. Compounds injected are most commonly aminophylline, isoproterenol and phosphatidylcholine however, many other compounds are used, largely “herbals” such as artichoke extract. Even better, one of the proponents of the therapy (that charges \$5000 for a 3-day training class) promotes the therapy for migraines, back pain, acne, insomnia and many others. Charge for treatments range from \$250-\$750 per treatment, usually 3-10 treatments required; and no guarantee’s it lasts forever. Boodman SG. Sticking it to fat? *Washington Post.com* 2005 Apr 26; p. HE01.

[http://www.washingtonpost.com/wp-](http://www.washingtonpost.com/wp-dyn/content/article/2005/04/25/AR2005042501163.html?referrer=email)

[dyn/content/article/2005/04/25/AR2005042501163.html?referrer=email](http://www.washingtonpost.com/wp-dyn/content/article/2005/04/25/AR2005042501163.html?referrer=email)



Repelling development ... The CDC has recommended two additional mosquito repellents, in addition to DEET. They are picaridin and oil of lemon eucalyptus. They have been shown to be safe and effective. The CDC’s main rationale appears to be the importance of using mosquito repellents (due to West Nile virus, etc) and that some people cannot tolerate using DEET-containing products.

Payne JW. More repellent: CDC lets in two new bug sprays. *Washington Post.com* 2005 May 10;p. HE01.
<http://www.washingtonpost.com/wp-dyn/content/article/2005/05/09/AR2005050901062.html?referrer=email>

Sales are not sleepy ... market update for Lunesta[®] (eszopiclone by Sepracor). For its first month on the market (April 4 to May 9) it has recorded >150,000 prescriptions, one of the fastest starts on record. For those of you who may not have seen the ads, they are mostly on late-night TV (pretty clever). A downside is that patients may be eschewing first-line nondrug therapies and going straight for the drugs.

Forelle C. Sepracor insomnia drug is early riser. *Wall Street Journal.com* 2005 May 13; p. B8.



Vocabulary ... **pseudobulbar affect**, also known as, emotional lability, emotional incontinence, uncontrollable laughing/crying or pathologic laughter/crying. The name comes from the proposed pathology originating in the brain stem. It is commonly associated with more severe diseases such as Alzheimer's disease, brain injury or multiple sclerosis. According to the article, this could be the next 'erectile dysfunction,' that is, a drug in search of a disease. The 'cure' is Neurodex[®] by Avanir which is a formulation of dextromethorphan and quinidine. The company is conducting trials to gain FDA approval for the indication. In an accompanying article, the rationale of the combination is described, basically a pharmacokinetic interaction that allows for dextromethorphan to remain in the body longer.

Pollack A. Marketing a disease, and also a drug to treat it. *New York Times.com* 2005 May 19.

<http://www.nytimes.com/2005/05/09/business/09avanir.html>?

Pollack A. A new use for two older drugs. *New York Times.com* 2005 May 19.

<http://www.nytimes.com/2005/05/09/business/09avanirbox.html>



Flu vaccine shortage!!! ... or not! Unfortunately, no one knows yet. The CDC is sticking by its report of April 1, anticipating some shortage and recommending that providers put in place a system like last year. Vaccinate the "priority" patients first, early, then add additional patients as dictated by the vaccine supply. However, a recent story indicates that there is a "feeding frenzy" surrounding the ordering of the vaccine, called "unprecedented" by a CDC official. Many of the concerns of last year are present, but many are ordering their supplies as early as they can to try to be prepared. Many of the local shortages were due to providers ordering too late and there was none to be had. I'm sure we'll hear more as the summer wears on.

CDC. Influenza vaccine prebooking and distribution strategies for the 2005-2006 influenza season. *MMWR* 2005 Apr 1;54(12):307-8.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5412a4.htm>

McKay B, Naik G. Rush to order flu vaccine is 'feeding frenzy.' *Wall Street Journal.com* 2005 May 4;p. B1.

AUBURN HSOP FACULTY in the literature ...

- Ukens C. The road less traveled. *Drug Topics* 2005 May 2;149(9):42-45.
<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=158409>
 - A former Auburn student, **Dr. Brent Fox** is one of the featured pharmacists in this article about seven different pharmacists and their unconventional career paths.

NEW RESOURCES in the DILRC ...

- Sweetman SC, ed. *Martindale: The Complete Drug Reference*. 34th ed. London: The Pharmaceutical Press, 2005.

The last “dose” ... In honor of our recent graduates ...

“A professor can never better distinguish himself in his work than by encouraging a clever pupil, for the true discoverers are among them, as comets amongst the stars.”

--Linnaeus [Carl von Linné] (1707-1778), *From biography by Theodor Magnus Fries, trans. Benjamin Daydon Jackson, ch. 9.*

*An electronic bulletin of drug and health-related news highlights, a service of ...
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